

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION  
OPIATE LITIGATION

This document relates to:

*The County of Summit, Ohio, et al. v. Purdue*  
*Pharma L.P., et al.*  
Case No. 18-op-45090

and

*The County of Cuyahoga v. Purdue Pharma*  
*L.P., et al.*  
Case No. 1:18-op-45004

---

MDL No. 2804

Hon. Judge Dan A. Polster

**REPLY BRIEF IN FURTHER SUPPORT OF DEFENDANTS' *DAUBERT***  
**MOTION TO EXCLUDE THE OPINIONS OF JONATHAN GRUBER**

**TABLE OF CONTENTS**

<b>TABLE OF CONTENTS .....</b>	<b>i</b>
<b>TABLE OF AUTHORITIES .....</b>	<b>ii</b>
<b>INTRODUCTION.....</b>	<b>1</b>
<b>ARGUMENT.....</b>	<b>1</b>
<b>I. GRUBER’S OPINIONS ARE NEITHER RELIABLE NOR THE PRODUCT OF GENERALLY ACCEPTED ECONOMIC PRINCIPLES AND METHODOLOGIES.....</b>	<b>1</b>
<b>II. GRUBER’S OPINIONS DO NOT FIT AND ARE IRRELEVANT. ....</b>	<b>5</b>
<b>CONCLUSION .....</b>	<b>6</b>

## **TABLE OF AUTHORITIES**

	<b>Page(s)</b>
 <b>Cases</b>	
<i>Daubert v. Merrell Dow Pharms., Inc.</i> , 509 U.S. 579 (1993) .....	3, 4, 5
<i>Gen. Elec. Co. v. Joiner</i> , 522 U.S. 136 (1997) .....	3
<i>Holesapple v. Barrett</i> , 5 Fed. App’x 177 (4th Cir. 2001) .....	2
<i>In re Mirena IUS Levonorgestrel-Related Prod. Liab. Litig.</i> , 341 F. Supp. 2d 213 (S.D.N.Y. 2018) .....	4
<i>Nelson v. Tenn. Gas Pipeline Co.</i> , 243 F.3d 244 (6th Cir. 2001) .....	4
<i>Presley v. Lakewood Eng’g &amp; Mfg. Co.</i> , 553 F.3d 638 (8th Cir. 2009) .....	3
 <b>Rules</b>	
Fed. R. Evid. 702.....	5
 <b>Expert Materials</b>	
Deposition Transcript of Jonathan Gruber .....	1, 2, 3
Expert Report of Jonathan Gruber.....	1, 4

## **INTRODUCTION**

Professor Gruber's key opinions are graphical depictions of statistics (for opioid use disorder (OUD), opioid mortality, and crime) comparing the U.S. counties in the top quartile for prescription opioid shipments with counties in the bottom quartile. *See* Gruber Rpt. at 55-61, 76-80, ¶¶ 79-87, 108-12. These depictions have no methodological underpinning, and Gruber admits that he presents them because they suggest stronger conclusions than might exist in the middle quartiles. *See* Gruber Tr. at 191:12-13. Yet Cuyahoga and Summit Counties are in the middle quartiles, and Gruber has performed no analysis to determine whether the effects that his graphs purport to show hold true in the middle quartiles generally, or for Cuyahoga and Summit Counties specifically. Although Plaintiffs claim that Gruber performed a regression analysis, his regression is completely unrelated to his key graphics, and is flawed on its own terms.

From these graphs, Gruber seeks to conclude that shipments *cause* OUD, mortality, and crime, but he has no analysis to support those conclusions and relies instead on what his graphs might misleadingly suggest to a lay jury. He cites a couple of epidemiological papers but is not an epidemiologist himself, and those papers do not even contain the graphs that Gruber seeks to sponsor. Nor do those papers bless his baseless methodology. Even if these flaws were not fatal already, Gruber addresses all shipments together, proper and allegedly improper, and makes no effort to determine whether any alleged Defendant misconduct caused any expenditures by the Counties. His opinions are neither reliable nor relevant and should be excluded.

## **ARGUMENT**

### **I. GRUBER'S OPINIONS ARE NEITHER RELIABLE NOR THE PRODUCT OF GENERALLY ACCEPTED ECONOMIC PRINCIPLES AND METHODOLOGIES.**

Plaintiffs seek to muddle Gruber's opinions in order to show that they are based on reliable and accepted methodologies. They emphasize that Gruber depicts basic graphical illustrations *and*

performs one regression analysis, hoping the Court will conclude that the latter supports the former. Yet Plaintiffs do not deny that the regression analysis is completely unrelated to Gruber's graphical illustrations. *See* Opp. at 9; Gruber Tr. at 175:12-177:1; 178:1-181:18.

The main sections of Gruber's report are comprised of quartile-based graphs comparing U.S. counties with the highest shipments of prescription opioids to U.S. counties with the lowest shipments. Gruber relies entirely upon the graphs to show differences between the highest and lowest quartiles in terms of OUD, overall opioid mortality, and crime. By his own admission, the purpose of his graphs is to show that the highest shipment quartile had higher OUD, mortality, and crime than the lowest shipment quartile. *See* Gruber Tr. at 267:3-8; 408:7-23. Gruber then opines that prescription opioid shipments *cause* OUD, mortality, and crime based upon these graphs. But saying it does not make it so. There is no underlying analysis (much less an accepted one) supporting that massive inferential leap; causation cannot be proven simply with a graph depicting data. *See Holesapple v. Barrett*, 5 Fed. App'x 177, 180 (4th Cir. 2001) (Expert opinion must "be connected to data by something more than the 'it is so because I say it is so' of the expert."). In addition, Cuyahoga and Summit Counties do not fall into either the highest or lowest quartile. The graphics therefore do not show causation even in the highest and lowest quartiles; they only misleadingly attempt to suggest it. And the graphics show nothing about the plaintiff Counties.

Plaintiffs ignore these fatal flaws and admit that "the thrust of Prof. Gruber's empirical analysis is to examine trends based on the 400-county sample set he analyzed, *not to focus on one or two counties.*" Opp. at 11 (emphasis added). Even if there were an underlying reliable methodology (which there is not) to support Gruber's graphic illustrations, Plaintiffs concede that Gruber has not analyzed the relationship between Defendants' alleged wrongdoing and alleged expenditures by Cuyahoga and Summit Counties (i.e. Plaintiffs' alleged injury). And although

Gruber does present limited data concerning the two Counties, *see* Opp. at 11, those graphs are entirely unrelated to his quartile graphs purporting to show causation. The County-specific graphs show only shipment levels (Figure I.10) and mortality levels (Figure I.11) in the Counties, and in fact undermine Gruber's key opinions by showing that on those two measures, both Counties diverge from national averages, and diverge also from each other. Moreover, no expertise is required to present that County-specific data, which appear on federal, state, and County websites. *See Presley v. Lakewood Eng'g & Mfg. Co.*, 553 F.3d 638, 646 (8th Cir. 2009) (excluding an expert opinion consisting of general observations).

Plaintiffs seek to justify Gruber's lack of focus on the two plaintiff Counties by claiming that "[i]f the relationship between [shipments and mortality] remained consistent across a variety of localities with different characteristics, then the inference that the number of shipments affected the harms would be valid." Opp. at 10. However, by comparing only the highest and lowest quartiles, Gruber's illustrations at most show only a relationship at the extremes. Gruber fails to show that the relationship holds true for the middle quartiles, which comprise 50 percent of the 400 large counties in the U.S., and certainly fails to show that the relationship holds true as to Cuyahoga and Summit Counties. Indeed, Gruber concedes that the purpose of his graphs is to show the relationship elsewhere in the country even if it does not hold in the two Counties: "We don't claim that every single observation lines up with what's shown in those central tendencies, but that's not the purpose." Gruber Tr. at 408:7-23. That is indefensible. To show a relationship only at the extremes, particularly without methodological support, is not helpful to the fact-finder; it is simply misleading and should be excluded. *See, e.g., Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) ("[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert.");

*In re Mirena IUS Levonorgestrel-Related Prod. Liab. Litig.*, 341 F. Supp. 2d 213, 242 (S.D.N.Y. 2018) (“[A]n expert may not ‘pick and choose’ from the scientific landscape and present the Court with what he believes the final picture looks like.”) (internal citations omitted).

Plaintiffs do not and cannot dispute that Gruber’s simplistic, misleading quartile-based graphs fail to control for numerous other potential causal factors, such as cancer incidence, prescription levels, and illegal fentanyl distribution. Without any underlying analysis, let alone by means of an accepted methodology, Gruber’s quartile-based graphs permit the plug-and-play causal connections that *Daubert* intended to exclude. The Sixth Circuit has excluded expert opinions for similarly failing to account for other casual factors. *See e.g., Nelson v. Tenn. Gas Pipeline Co.*, 243 F.3d 244, 253 (6th Cir. 2001) (excluding expert opinion because it ignored other factors that could have caused plaintiff’s symptoms). This Court should do the same.

Plaintiffs try to overcome Gruber’s methodological deficiencies by pointing to an unrelated, stand-alone regression analysis that he performed. But that rudimentary regression analysis purports only to show that there was variation in the quantities of prescription opioids shipped to 400 large U.S. counties, and that the variation is only partly explained by certain economic factors. *See* Gruber Rpt. at 49-54, ¶¶ 73-77. The results of that regression are reflected in Gruber Figures I.14 and I.15, and do not even purport to provide any basis for the quartile-based graphics Gruber uses to try to show causation. Importantly, the fact that there is variation in shipments among 400 U.S. counties says nothing about Cuyahoga and Summit Counties, nor does it say anything about the reasons for such variation.

Plaintiffs also argue that Gruber’s reference to a few economic and epidemiological studies supports his opinions. Defendants address these and other studies in detail in their *Daubert* briefing concerning Plaintiffs’ “gateway hypothesis” of causation. *See* Dkt. Nos. 1857 and 2446.

It is worth mentioning here, however, that none of the literature cited by Gruber contains the misleading and unsupported quartile-based graphics that he seeks to present here.

It is one thing, and often acceptable, to illustrate the results of an otherwise rigorous analysis with charts and graphs. Plaintiffs' opposition brief cites examples allowing this approach. But that is not what Gruber did here. Experts may not present misleading graphs and charts of sliced data with no underlying, methodologically accepted analysis. That is precisely what Gruber has done in his report, and the result is purely speculative graphical illustrations that do not meet the requirements of *Daubert* and Rule 702. Accordingly, Gruber's opinions are unreliable and should be excluded.

## **II. GRUBER'S OPINIONS DO NOT FIT AND ARE IRRELEVANT.**

Plaintiffs do not dispute that Gruber failed to identify and link purportedly wrongful shipments to specific harms and expenditures in Cuyahoga and Summit Counties. Indeed, Plaintiffs admit that Gruber was not asked to analyze Defendant-specific conduct nor County-specific harms. Opp. at 15. Plaintiffs nonetheless ask the Court to accept Gruber's mere assertion that greater prescription opioid shipments caused increased harms and expenditures, without more. They seek to justify this unsupported opinion simply by claiming that the "opioid epidemic in the Bellwether Counties is part of a larger nationwide crisis." Opp. at 16. According to Plaintiffs, their experts, including Gruber, need not "analyze the injuries in Summit and Cuyahoga Counties without reference whatsoever to the similar injuries in other places in the country." *Id.*

This justification for overinclusion, however, does not permit Plaintiffs' experts to avoid having to establish a causal chain from Defendants' purported misconduct through to expenditures by the plaintiff Counties. Plaintiffs' argument that Gruber's opinions are reliable ignore the most fundamental flaws in his analysis: namely, that he fails to analyze altogether Defendants' purported misconduct, and fails to establish proximate causation through to expenditures by



Summit and Cuyahoga Counties. Gruber's graphics represent nationwide averages for quartiles that do not include the plaintiff Counties. Gruber's attempt to use aggregate averages for other locations to attribute complex, multi-faceted societal harms in Cuyahoga and Summit to the Defendants is premised on completely unsupported assumptions, and is highly misleading to boot.

Plaintiffs' opposition confirms that Gruber only graphically portrayed prescription opioid shipments in the aggregate using data from 400 counties across the country. At no point has Gruber analyzed causation running from allegedly improper shipments into Cuyahoga and Summit Counties through to expenditures by those Counties. He also makes no effort to separate medically appropriate shipments from shipments that purportedly resulted from misconduct, or even to distinguish the opioid shipments manufactured by Defendants versus others. Instead, Gruber combines all prescription opioid shipments from both Defendants and non-defendants—whether alleged to have been caused by misconduct or not—in his 400-county sample and combines all opioid mortality (both licit and illicit) in those 400 counties. Gruber therefore cannot opine that there is a causal relationship between any alleged wrongdoing by the Defendants and any alleged harm to the plaintiff Counties. His opinions do not “fit” and are irrelevant to Plaintiffs' claims, and should be excluded.

### **CONCLUSION**

For the foregoing reasons, as well as those stated in our moving brief, the Court should exclude Gruber's opinions and proposed testimony.

Dated: August 16, 2019

Respectfully submitted,

BY: /s/ Mark S. Cheffo  
Mark S. Cheffo  
DECHERT LLP  
Three Bryant Park  
1095 Avenue of the Americas  
New York, NY 10036  
Telephone: (212) 698-3500  
Mark.Cheffo@dechert.com

*Counsel for Defendants Purdue Pharma L.P.,  
Purdue Pharma Inc., and The Purdue Frederick  
Company*

*Co-Liaison Counsel for the Manufacturer  
Defendants<sup>1</sup>*

/s/ Carole S. Rendon  
Carole S. Rendon  
BAKER & HOSTETLER LLP  
Key Tower 127 Public Square, Suite 2000  
Cleveland, OH 44114-1214  
Telephone: (216) 621-0200  
Fax: (216) 696-0740  
crendon@bakerlaw.com

*Counsel for Defendants Endo Health Solutions  
Inc. and Endo Pharmaceuticals Inc.; Par  
Pharmaceutical, Inc., and Par Pharmaceutical  
Companies, Inc.*

*Co-Liaison Counsel for the Manufacturer  
Defendants*

---

<sup>1</sup> Teva Pharmaceutical Industries Ltd., Allergan plc, and Mallinckrodt plc are respectively an Israeli corporation, Irish holding company, and an Irish company that are not subject to and contest personal jurisdiction for the reasons explained in their motions to dismiss for lack of personal jurisdiction; they are specially appearing to join this motion, and, thus, they do not waive and expressly preserve their personal jurisdiction challenges.

/s/ Enu Mainigi

Enu Mainigi  
WILLIAMS & CONNOLLY LLP  
725 Twelfth Street, N.W.  
Washington, DC 20005  
Telephone: (202) 434-5000  
Fax: (202) 434-5029  
emainigi@wc.com

*Counsel for Defendant Cardinal Health, Inc.*

*Co-Liaison Counsel for the Distributor Defendants*

/s/ Shannon E. McClure

Shannon E. McClure  
REED SMITH LLP  
Three Logan Square  
1717 Arch Street, Suite 3100  
Philadelphia, PA 19103  
Telephone: (215) 851-8100  
Fax: (215) 851-1420  
smcclure@reedsmith.com

*Counsel for Distributor Defendant  
AmerisourceBergen Drug Corporation*

*Co-Liaison Counsel for the Distributor Defendants*

/s/ Geoffrey Hobart

Geoffrey Hobart  
COVINGTON & BURLING LLP  
One CityCenter  
850 Tenth Street, NW  
Washington, DC 20001-4956  
Telephone: (202) 662-5281  
ghobart@cov.com

*Counsel for Distributor Defendant  
McKesson Corporation*

*Co-Liaison Counsel for the Distributor Defendants*

/s/ Kaspar Stoffelmayr

Kaspar Stoffelmayr

BARTLIT BECK LLP

54 West Hubbard Street

Chicago, IL 60654

Telephone: (312) 494-4434

Fax: (312) 494-4440

kaspar.stoffelmayr@bartlitbeck.com

*Counsel for the Walgreens Defendants*

*Liaison Counsel for the Chain Pharmacy  
Defendants*

**CERTIFICATE OF SERVICE**

I, Geoffrey E. Hobart, hereby certify that the foregoing document was served via  
the Court's ECF system to all counsel of record.

/s/ Geoffrey E. Hobart

GEOFFREY E. HOBART